

Regulatory Scientists Office of Clinical Pharmacology and Biopharmaceutics Food and Drug Administration

The Food and Drug Administration is seeking regulatory scientists to serve as reviewers in the Office of Clinical Pharmacology and Biopharmaceutics (OCPB) in Rockville, MD. Responsibilities include the review of biopharmaceutic, pharmacokinetic and pharmacodynamic protocols and data across a spectrum of therapeutic drug classes received from the pharmaceutical industry as part of Investigational New Drug (IND) and New Drug Application (NDA) submissions. As an ongoing part of the regulatory review process, the reviewer interacts with the sponsor to facilitate drug development, and determines the acceptability of the data in the submission. These decisions have a direct impact on the safety, efficacy and quality of drug products reaching the U.S. consumer and on the future research efforts by the pharmaceutical industry. Reviewers are encouraged to participate in scientific initiatives to develop guidances which promote efficient drug development and good review practices.

HIGHLY DESIRABLE: Ph.D. in pharmacokinetics/biopharmaceutics or Pharm.D. with pharmacokinetic training/experience, thorough knowledge of pharmacokinetics, biopharmaceutics, pharmacodynamics, analytical methods and statistical analysis.

SALARY: Salary level is determined by candidate's education and experience. Additional bonuses above the base salary may be applicable.

TYPES OF POSITIONS: The positions may either be filled under the Civil Service System which requires U.S. citizenship, under the Service Fellowship Program which requires U.S. permanent residency, or under the Visiting Associate Program which does not require U.S. permanent residency. Commission in the U.S. Public Health Service, and commensurate pay scale, may also be available.

Submit detailed resume or curriculum vitae for review to:

DHHS/PHS/Food and Drug Administration Room 225; HFD-64 7520 Standish Place; SRC 96060 Rockville, MD 20855 ATTENTION: Recruitment Staff

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